Remarks/Arguments:

Newly presented claims 11-26 are pending. Claims 1-10 are cancelled without prejudice or disclaimer, with claims 1-4, 9, and 10 being cancelled pursuant to restriction.

Present claims 11-26 are directed to the invention elected pursuant to the restriction requirement and contained subject matter found in the originating claims.

Claims 5-8 were rejected under 35 USC 112, second paragraph, as allegedly being indefinite. For essentially the same reasons, claims 5-8 were rejected under 35 USC 101 as allegedly constituting non-statutory subject matter. Reconsideration of the rejections is requested, in view of the changes to the claims effected hereby.

The present claims are directed to a "method," and they affirmatively recite the method step "administering." Accordingly, the present claims satisfy the requirements of § 112, ¶ 2 and § 101. Withdrawal of the rejections under § 112, ¶ 2 and § 101 appears to be in order.

Claims 5-7 were rejected under 35 USC 102(b) as allegedly anticipated by US6228891 (Enzmann) as supported by an alleged admission of prior art. Reconsideration of the rejection is requested.

Enzmann teaches the treatment of different diseases with Q10, for example, use of Q10 for the treatment of diseases of the cardiovascular system, the lung, the muscles, asthma, and the like. Applicants note that Enzmann does not teach treating "bronchoconstriction of the lung" as alleged by the PTO (Office Action, page 3, last paragraph).

The PTO alleges that teaching *histamine is a central mediator of inflammatory reactions* in the instant specification constitutes an admission of prior art. In view of the foregoing allegation, the PTO alleges that Enzmann *inherently* discloses influencing the activity of histamines, i.e., the PTO relies on the *doctrine of inherency*, to maintain the rejection under §102(b). With all due respect, the PTO is mistaken.

For the doctrine of inherency to apply it must be "*inevitable*" from the teachings of the prior art. *In re Wilding*, 190 USPQ 59, 62 (CCPA 1976) (*emphasis added*). "In relying on a theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (*emphasis in original*). Before "the burden shifts," the examiner has "the initial burden of establishing a prima facie basis for the alleged inherency." 17 USPQ2d at 1463-64. To base a rejection on what is allegedly inherent in the reference teachings,

> the examiner must . . . reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the applied prior art.

17 USPQ2d at 1464 (*emphasis original*). An argument by the PTO is "not prior art." *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

"An accidental or unwitting duplication of an invention cannot constitute an anticipation." *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978) (had anyone followed the teachings of the cited reference and received the benefit of the rejected claims, "it was an unrecognized accident," 198 USPQ at 346, because nothing in the reference inherently suggests such a benefit). "New uses of

old products or processes are indeed patentable subject matter." *Perricone v. Medicis Pharmaceutical Corp.*, 77 USPQ2d 1321, 1328 (Fed. Cir. 2005).

Some diseases of the cardiovascular system (in particularly asthma) are inflammatory related. Nevertheless, a physician does not *inevitably* use an *anti-histamine* to treat such diseases. Accordingly, although Enzamann uses Q10 to treat, e.g., asthma, nothing in the reference teaches or suggests that Enzamann uses Q10 as an anti-histamine; in other words, Enzmann does not evidence prior art knowledge of Q10 having pharmaceutically effective anti-histamine properties.

The PTO fails to even allege that use of Q10 as an anti-histamine is *inevitable* from Enzmann's teachings—let alone "provide" the requisite "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent [anti-histamine] characteristic *necessarily* flows from the teachings of the applied prior art." *Levy*, 17 USPQ2d at 1464 (*emphasis original*). As such, the §102(b) rejection over Enzmann cannot be maintained because the PTO has failed to satisfy its "initial burden of establishing a prima facie basis for the alleged inherency." 17 USPQ2d at 1463-64. Mere argument by the PTO is "not prior art." *Rijckaert*, 28 USPQ2d at 1957.

Moreover, since the beneficial anti-histamine *use* recited in the rejected (and present) claims is neither taught nor suggested by Enzmann, had anyone followed the teachings of the cited reference and received the beneficial use/effect set forth in the instant claims "it was an unrecognized accident," *Marshall*, 198 USPQ at 346, because no teaching in the reference inherently suggests such a benefit. Since the reference disclosure constitutes "accidental or unwitting duplication" of the presently claimed invention, it "cannot constitute an anticipation." *Marshall*, 198 USPQ at 346.

Similarity of the present facts with those in *Perricone, supra*, renders the decision particularly in point. As stated in *Perricone*, 77 USPQ2d at1328 (emphasis added) (*emphasis original*):

> Claim 1 . . . recites a new use of the composition disclosed by [the prior art], i.e., the treatment of skin sunburn. The district court's inherent anticipation analysis for this claim contains a flaw . . . [and] goes astray because it assumes what [the prior art] neither disclosed nor rendered inherent. Because [the prior art] does not disclose topical application *to skin sunburn*, this court reverses the district court's holding that [the prior art] anticipates [the] claims.

Likewise, because Enzmann "does not disclose" the claim limitation *influencing the activity of an inflammatory mediator*, the PTO's "inherent anticipation analysis . . . contains a [fatal] flaw."

For the foregoing reasons, the PTO has failed to show that use of Q10 as an *anti-histamine* is "inevitable" from—and, so, *inherent* in—the teachings of Enzmann, *Wilding*, 190 USPQ at 62, and since the reference disclosure constitutes "accidental or unwitting duplication" of the presently claimed invention, it "cannot constitute an anticipation." *Marshall*, 198 USPQ at 346. The presently claimed "New uses of old products . . . are indeed patentable subject matter." *Perricone*, 77 USPQ2d at 1328. Withdrawal of the rejection under §102(b) appears to be in order.

Claims 5-8 were rejected under 35 USC 102(e) as allegedly anticipated by US2002/0032160 (Nyce) as supported by an alleged admission of prior art. Reconsideration of the rejection is requested.

Nyce allegedly discloses influencing histamine. That is, because Nyce discloses inflammatory related diseases, and in view of the alleged prior art admission (discussed above), the PTO alleges that Nyce *inherently* discloses influencing the activity of histamines, i.e., the PTO relies

on the *doctrine of inherency* to maintain the rejection under §102(e)—in the same manner as Enzmann was relied on in the §102(b) rejection (above). With all due respect—for essentially the same reasoning (above) traversing the §102(b) rejection—the PTO is mistaken.

Nyce neither teaches nor suggests an anti-histamine effect, allegations to the contrary in the statement of rejection notwithstanding.

Nyce discloses the treatment of side effects associated with an efficacious adenosine-depletion treatment. According to Nyce (¶ [0010]) treating asthma and the like by effecting adenosine depletion (in the treated subject) causes "a broad variety of deleterious conditions" (i.e., negative side effects). Nyce discloses treating these negative side effects with a composition containing dihydroepiandrosterone together with ubiquinone. The reference mentions nothing—explicitly or implicitly—about an anti-histamine effect.

The PTO fails to even allege that use of Q10 as an anti-histamine is *inevitable* from Nyce's teachings—let alone "provide" the requisite "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent [anti-histamine] characteristic *necessarily* flows from the teachings of the applied prior art." *Levy*, 17 USPQ2d at 1464 (*emphasis original*). As such, the §102(e) rejection over Nyce cannot be maintained because the PTO has failed to satisfy its "initial burden of establishing a prima facie basis for the alleged inherency." 17 USPQ2d at 1463-64. Mere argument by the PTO is "not prior art." *Rijckaert*, 28 USPQ2d at 1957.

Moreover, since the beneficial anti-histamine *use* recited in the rejected (and present) claims is neither taught nor suggested by Nyce, had anyone followed the teachings of the cited reference and

received the beneficial use/effect set forth in the instant claims "it was an unrecognized accident," *Marshall*, 198 USPQ at 346, because no teaching in the reference inherently suggests such a benefit. Since the reference disclosure constitutes "accidental or unwitting duplication" of the presently claimed invention, it "cannot constitute an anticipation." *Marshall*, 198 USPQ at 346.

For the foregoing reasons, the PTO has failed to show that use of Q10 as an *anti-histamine* is "inevitable" from—and, so, *inherent* in—the teachings of Nyce, *Wilding*, 190 USPQ at 62, and since the reference disclosure constitutes "accidental or unwitting duplication" of the presently claimed invention, it "cannot constitute an anticipation." *Marshall*, 198 USPQ at 346. The presently claimed "New uses of old products . . . are indeed patentable subject matter." *Perricone*, 77 USPQ2d at 1328. Withdrawal of the rejection under §102(e) appears to be in order.

For the record, the office action (page 4) states "Applicant's admission of the prior art includes the statement that histamines, PAF, and leukotrienes are central mediators of inflammatory reactions (pg. 1 and 3)," but leaves to speculation what constitutes (other than the mentioned "statement") the alleged admission of prior art; and, being left to speculation, it is the same as if no such allegation were made. Accordingly, the only application text of relevance in connection with the alleged admission is "Histamines are amoung the central mediators of inflammatory reactions" (at page 1) and "Other mediators are those mediators which are also released as a response in inflammatory processes, especially PAF (platelet activating factor), leukotrienes as well as SRS-A (slow-reacting substance of anaphylaxis)" (at page 3), i.e., nothing more than provided by the quoted text, on its face, is relevant to the alleged admission of prior art.

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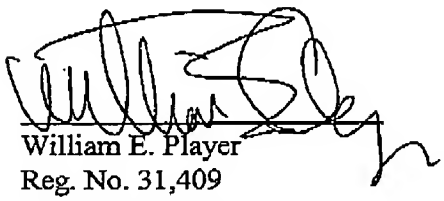
Favorable action is requested.

Respectfully submitted,



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